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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/767,296

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EXAMINER

WOO, JULIAN W

ART UNIT

PAPER NUMBER

3773

MAIL DATE

DELIVERY MODE

11/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/767,296	Applicant(s) YAN, JOHN Y.	
	Examiner Julian W. Woo	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/22/08.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28,29,31,32 and 41-53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28,29,31,32 and 41-53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/22/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 28, 41, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (5,607,463). Schwartz et al. disclose the invention substantially as claimed. Schwartz et al. disclose, at least in the figures and in col. 7, line 20 to col. 8, line 50; col. 9, lines 19-60; and col. 8, lines 30-39; a stent comprising a strut element (from the Wiktor stent) including a solid metallic inner core having opposed inner and outer sides and an outer layer disposed on the outer side, where the outer layer is made from a first porous metallic material (e.g., tantalum), where the inner layer is made from a porous metallic material, where the strut is formed from a sheet, where the solid core causes fluid in the second porous layer to flow in a radially inward direction, where the stent is configured for being radially expanded by a balloon and for

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providing support to a body vessel, and where the inner and outer layers are loaded with respective first (e.g., heparin) and second therapeutic agents (e.g., “antiplatelet agents, anticoagulant agents, antimicrobial agents, antimetabolic agents, anti-inflammatory agents and other drugs”). However, Schwartz et al. do not specifically disclose that the inner layer comprises a second metallic material. Nevertheless, Schwartz et al. disclose, in col. 7, lines 53-40; various metallic materials (“e.g., tantalum, niobium, gold, or platinum”) applicable to inner and outer layers of the stent. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply a second metallic material to the inner layer, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

3. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (5,607,463) in view of MacGregor (4,458,366). Schwartz et al. disclose the invention substantially as claimed, but do not disclose that at least one of the first and second porous metallic materials is made from sintered particles, filaments or fibers. MacGregor teaches, at least in figures 1 and 2 and in col. 2, line 57 to col. 4, line 68 and col. 5, line 28 to col. 6, line 2, an implantable device that contacts blood, where the device includes an inner layer (34) or a porous layer facing radially inward that is disposed on a solid metallic core (36) and comprises a sintered metallic material (e.g., a metal hydride according to col. 5, lines 49-53). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of MacGregor,

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to include an inner layer of sintered metallic material. Such a layer would reduce the risk of thromboembolism from blood contacting the inner surfaces of the stent.

4. Claims 31, 42-45, 48, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (5,607,463) in view of Kleshinski et al (5,540,712). Schwartz et al. discloses the invention substantially as claimed. Schwartz et al. disclose a stent comprising a solid metallic region or solid core, a porous metallic region or porous layer, and opposing or opposed first and second ends disposed along (i.e., adjacent to or alongside) a longitudinal axis of the stent, where the first and second ends are opposing ends of a cylindrical sheet (the metal layer and/or an elastomeric film), where the stent is configured for being radially expanded by a balloon and for providing support to a body vessel, where the porous layers are adapted for being loaded with a therapeutic agent. However, Schwartz et al. do not disclose that the stent has a longitudinal seam or a weld. Kleshinski et al. teach, at least in col. 3, line 53 to col. 4, line 7; a stent with a longitudinal seam (along 6) or a weld. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Kleshinski, to construct the stent of Schwartz et al., so that it has a seam or weld. Such a construction would allow improved scaffolding or stress on a blood vessel wall for holding the vessel lumen open. Schwartz et al. also do not disclose that the pore size of the porous metallic region is 2 to 4 microns. Nevertheless, it would have been obvious to one having ordinary skill in the art at the time the invention was made to size the pores as claimed, since it has been held that where the general conditions of

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a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art.

5. Claims 32 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (5,607,463) in view of Kleshinski et al. (5,540,712), and further in view of MacGregor (5,171,262). Schwartz et al. in view of Kleshinski et al. disclose the invention substantially as claimed, but do not disclose that the first porous layer is formed from sintered particles, filaments or fibers. MacGregor teaches, at least in col. 5, lines 55-64; a stent with a porous layer of sintered particles. It would have been obvious to one having ordinary skill in the art at the time the invention was made, to modify the first porous layer of the stent of Schwartz et al. in view of Kleshinski et al., so that it is formed from sintered particles. Such a layer would allow therapeutic coatings to be applied to the stent and securely and mechanically bonded to the stent.

6. Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (5,607,463) in view of Kleshinski et al. (5,540,712), and further in view of MacGregor (4,458,366). Schwartz et al. in view of Kleshinski et al. disclose the invention substantially as claimed, but do not disclose that the second porous layer is formed from sintered particles, filaments or fibers. MacGregor teaches, at least in figures 1 and 2 and in col. 2, line 57 to col. 4, line 68 and col. 5, line 28 to col. 6, line 2, an implantable device that contacts blood, where the device includes an inner layer (34) or a porous layer facing radially inward that is disposed on a solid metallic core (36) and comprises a sintered metallic material (e.g., a metal hydride according to col. 5, lines 49-53). It would have been obvious to one having ordinary skill in the art at the time the

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invention was made, in view of MacGregor, to modify the second layer of the stent of Schwartz et al. in view of Kleshinski et al., so that it is formed of sintered metallic material. Such a layer would reduce the risk of thromboembolism from blood contacting the inner surfaces of the stent.

7. Claims 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. (5,607,463) in view of Khosravi et al. (5,441,515). Schwartz et al. disclose the invention substantially as claimed, but do not disclose that the coiled stent includes a head portion, at least two slots and tail portions receivable in the slots. Khosravi et al. teach, at least in figure 26, a stent including a head portion, at least two slots (395) and tail portions (390) receivable in the slots. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Khosravi et al., to modify the stent of Schwartz et al., so that it has a head portion, at least two slots and tail portions receivable in the slots. Such a modification would allow the stent to be inserted into a body lumen, to be expanded, and to be reliably locked in an enlarged diameter form for maintaining the patency of the body lumen.

Response to Amendment

8. Applicant's arguments with respect to claims 28, 29, 31, 32, and 41-53 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/

Primary Examiner, Art Unit 3773

November 7, 2008